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UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. RAMESH "SUNNY" BALWANI, Defendant.	Case No. CR-18-00258-EJD **DEFENDANT RAMESH "SUNNY" BALWANI'S REPLIES IN SUPPORT OF HIS MOTIONS IN LIMINE** **Date: January 6, 2022** **Time: 9:00 a.m.** **CTRM.: 4, 5th Floor** **Hon. Edward J. Davila**

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REPLY IN SUPPORT OF MOTION IN LIMINE NO. 1: UNMODIFIED COMMERCIAL DEVICES

The government's charges hinge on allegedly inaccurate and unreliable Theranos technology—the proprietary fingerstick analyzer and commercial devices modified to analyze fingerstick samples. Evidence that goes to the alleged inaccuracy and unreliability of non-Theranos technology is thus irrelevant and prejudicial.

The government opposes Mr. Balwani's motion to exclude that evidence even though one of its own motions asks the Court to exclude evidence on precisely the same basis. *See* Dkt. 1155 at 19–20. The government cannot have it both ways. Its opposition turns on vague generalities, speculation, and, in some places, outright misstatements meant to prove that the Indictment charges Mr. Balwani with crimes beyond the alleged inaccuracy and unreliability of Theranos technology. But a plain reading of the Indictment makes clear that the alleged schemes to defraud investors and patients extend only to the allegation that Theranos' proprietary technology could not consistently produce accurate and reliable results. This reading also tracks the government's own understanding in a string of submissions to this Court.

The government put it well: Evidence of the accuracy of tests not "run on [a] Theranos proprietary blood analyzer [but on] a regular FDA-approved machine" is irrelevant and "should be precluded under Rules 401 and 403." Dkt. 1155 at 20; *see also* Dkt. 1144 at 4 (quoting the language related to "Theranos's technology" in paragraph 16 of the Indictment to argue that "[the customer feedback] reports are irrelevant to the charged conduct in the TSI as they largely do not relate to the capabilities of Theranos's technology."). And, as the government also expressly acknowledges, when it comes to laying a foundation, "[r]elevance cannot be speculative." Dkt. 1155 at 20. The Court should grant Mr. Balwani's motion.

The Indictment's plain language. To start, the government "does not dispute that the relevant sections of the Indictment also make allegations about problems with 'Theranos's technology.'" Dkt 1181 at 2. It contends, however, that the Indictment's language is "broader" and includes "allegations about Theranos' abilities as a whole." *See id.* Yet the government fails to tether its "broader" view to any specific language in the Indictment. *See id.* at 1, 2.

This failure gives the game away. In reality, the entire Indictment equates "Theranos's technology" with Theranos' proprietary fingerstick technology, not conventional commercial testing. The Indictment first defines Theranos' proprietary technology to include the TSPU. *See* Dkt. 469, Third Superseding Indictment ("TSI") ¶ 5. It next distinguishes Theranos' "proprietary methods and technologies" from "conventional blood testing." *See* TSI ¶ 6. The next paragraph refers to Theranos' fingerstick technology when discussing "Theranos's supposed technological and operational capabilities." *See* TSI ¶ 7. Then, the Indictment alleges the existence of media advertising about "the capabilities of Theranos's technology" and references testing from "a single small blood sample." *See* TSI ¶ 8. Allegations about the content of Theranos' website center on representations about Theranos' fingerstick testing—"its technology." *See* TSI ¶ 9. So too with allegations about the Theranos–Walgreens partnership. *See* TSI ¶ 10. The Indictment's list of alleged misrepresentations to investors contains still more language tying the charges to Theranos' proprietary fingerstick analyzers. *See, e.g.*, TSI ¶¶ 12(A), 12(C), 12(F), and 12(H).

The Indictment puts it succinctly—in language the government quotes only selectively:

> Despite representing to doctors and patients that Theranos could provide accurate, fast, reliable, and cheap blood tests and test results, HOLMES and Balwani knew—through, among other means, their involvement in Theranos's day-to-day operations and their knowledge of complaints received from doctors and patients—that ***Theranos's technology*** was, in fact, not capable of consistently producing accurate and reliable results. ***In particular***, HOLMES and BALWANI knew that Theranos was not capable of consistently producing accurate and reliable results for certain blood tests . . . [that are supposed to be examples of inaccurate and unreliable tests run on 'Theranos's technology'].

TSI ¶ 16 (emphasis added). The government's selective quotation surgically omits the language clarifying that the references to Theranos' ability to produce accurate and reliable blood test results relate to "Theranos's technology." *See* Dkt. 1181 at 2.

The Indictment also alleges that Mr. Balwani "transmitted, caused to be transmitted, or otherwise delivered to doctors and patients Theranos blood test results where HOLMES and BALWANI knew that the tests performed on ***Theranos technology*** contained or were likely to contain" inaccuracies and improperly manipulated results. TSI ¶ 17(C) (emphasis added).

The government contests none of this. Nor can it. Instead, it insists that a reading of the Indictment as a whole somehow fixes the problem, and argues that Mr. Balwani's reading is

"overly narrow and hyper-technical." Dkt. 1181 at 1. But there is no reading of the Indictment at any level of generality that does not link the allegations of inaccuracy and unreliability to Theranos' proprietary fingerstick testing technology. The Indictment refers throughout to Theranos' technology with specificity. It makes no specific reference to the accuracy and reliability of non-Theranos technology. Thus, reading the Indictment "as a whole" just cements Mr. Balwani's understanding that evidence of the accuracy and reliability of non-Theranos technology is irrelevant and prejudicial. *Id.* at 2.

Besides the plain language of the Indictment, the government's own submissions make clear that it all along intended only to charge Mr. Balwani with fraud related to the accuracy and reliability of "Theranos's technology."

Dr. Master's report. The government retained Dr. Stephen Master to provide expert testimony. His March 2020 report reflects that the government limited his analysis to assessing Theranos' technology rather than testing on unmodified commercial devices. *See* Ex. 52 (Master Report) at 11.[1] That limitation shows that, until now, the government has always viewed the charges against Mr. Balwani as relating only to Theranos' technology.

Dr. Master's report also confirms that the government mistakenly thought that HIV testing at Theranos ran on fingerstick technology. HIV was in the list of tests the government asked Dr. Master to opine on. *Id.* at 2–3 ("I was asked to provide opinions on whether Theranos was … able to produce accurate and reliable ***fingerstick*** results for tests such as … HIV …." (emphasis added)). The government's claim that it meant to charge fraud over the use of non-Theranos technology flatly contradicts the record.

The government's response to Ms. Holmes' efforts to exclude the CMS report. The government's arguments in response to Ms. Holmes' efforts to exclude the CMS evidence also confirm that the government's theory of relevance links to Theranos' proprietary fingerstick testing, and not to unmodified commercial device testing. In opposing Ms. Holmes' motion, the government referenced CMS' findings on fingerstick testing: (1) "*Theranos's blood analyzer*

[1] Unless otherwise noted, all exhibits cited are attached to the concurrently filed Declaration of Jeffrey B. Coopersmith.

repeatedly failed quality control checks"; (2) "*Theranos's blood analyzer* repeatedly produced values outside of ranges *Theranos* deemed acceptable"; and (3) "quality control results for *analyzers* were showing coefficients of variation between 18.7% and 63.6% during certain periods in 2014." Dkt. 675 at 1 (emphasis added). The government asserts that these CMS findings "put the lie to Defendant's grandiose claims about *Theranos's technology*." *Id.* at 2 (emphasis added).

The government's motion in limine no. 12. The government's own evidentiary requests drive home that the case against Mr. Balwani extends to the accuracy and reliability only of Theranos' technology. The government has moved to preclude Mr. Balwani from offering evidence that his mother received a Theranos blood test without the necessary foundation. Dkt. 1155 at 19–20. "Defendant Balwani has not provided," so the government contends, "basic foundational evidence demonstrating whether his mother's blood test from Theranos would tend to prove the accuracy or reliability of Theranos's proprietary blood analyzer." *Id.* The government's motion asserts that tests not "run on [a] Theranos proprietary blood analyzer [but on] a regular FDA-approved machine" are not relevant. Dkt. 1155 at 20. The government then argues that on this basis, "the Court should preclude Defendant Balwani from offering evidence that his mother received a Theranos test given that he cannot demonstrate foundational relevance to the charged conduct in the Third Superseding Indictment." *Id.*

The government's argument applies equally to its own evidence. When a party cannot link proffered evidence of the accuracy and reliability of a blood test to Theranos' technology, that evidence is inadmissible. *See* Dkt. 1179 at 12–13. But the government cannot wriggle out of its own reasoning just because the shoe is now on the other foot. Under the government's own logic and based on the TSI and the government's own expressed understanding of it, any evidence of alleged inaccuracy and unreliability of non-Theranos technology cannot be admitted. This includes testimony from patients E.T. and B.B., the CMS cover letter (Trial Ex. 4621A), and portions of the CMS Report. *See* Dkt. 1157 at 84–105 (Exs. 17, 18).

Patient E.T. Both parties now agree that HIV testing was never conducted on Theranos' technology. *See* Dkt. 1181 at 2–3. Still, the government argues that Patient E.T.'s testimony

should not be excluded. *Id.* But if the Court follows the government's own logic that tests not "run on [a] Theranos proprietary blood analyzer [but on] a regular FDA-approved machine" are irrelevant, then Patient E.T., who received a standard commercial HIV test, must be excluded. *See* Dkt. 1155 at 20.

The government makes two main arguments opposing the exclusion of Patient E.T. Dkt. 1181 at 2–3. The first is that the Indictment as a whole charges deficiencies in Theranos' lab testing practices generally, which encompasses commercial testing. *Id.* As addressed above, that is simply not true.

The second is that central to Mr. Balwani and Ms. Holmes' "shared scheme to defraud patients" is the notion that "they caused investors and patients to believe that Theranos' tests were *more* accurate than the conventional tests previously available through competing labs." *Id.* at 3. Their reference to "Theranos' tests" here encompasses HIV tests, which they admit were run on commercial machines. *Id.*

To start, this argument misses the point. The point—as the government argues in its own motion—is that only evidence of the accuracy of Theranos' proprietary fingerstick technology is admissible. Dkt. 1155 at 20. Even if it were otherwise, to support the superior accuracy claim that Mr. Balwani allegedly made to "investors and patients," the government cites a September 2013 *Wall Street Journal* article and says that "it is readily apparent that claims of superior accuracy were material to patients' decisions to patronize the new lab." Dkt. 1181 at 3. But nowhere does the government show that Patient E.T. read that article, was influenced by that article, or was in any way affected by reporting in the *Wall Street Journal* about superior accuracy. The *Wall Street Journal* article does not even make claims about superior accuracy for non-Theranos technology. *See* Ex. 59 (Trial Exhibit 1106). So that evidence fails to explain why Patient E.T.'s testimony is relevant.

The government's citation to Dr. Das' testimony in the Holmes trial—and specifically Exhibits 1333 and 5726—as evidence that the inaccuracy of the HIV assay is relevant to the charges reflects similarly tortured reasoning. *See* Dkt. 1181 at 3. To start, Dr. Das' testimony was elicited *by the defense* on cross-examination to show that Ms. Holmes hired Dr. Das to find and

fix problems in the lab, and he did as asked. Ex. 51 (11/10/21 Trial Tr. 5993:16—5996:11). The exhibit used to launch the testimony, Exhibit 13333, is a defense exhibit introduced by Ms. Holmes, again to show her purpose in hiring Dr. Das. And Exhibit 5726—cited in the government's declaration supporting its oppositions—which purportedly inserted into the Holmes trial deficient lab practices for HIV, was in fact neither introduced nor admitted into evidence in the Holmes trial. *See* Dkt. 1183-1. In any event, nothing in Exhibits 13333 or 5726 proves or even suggests that HIV was ever run on Theranos' technology, and the government does not claim otherwise. Patient E.T. must be excluded.

Moreover, the government's opposition neither contests nor responds to Mr. Balwani's Rule 403 arguments about the prejudice of the evidence on the inaccuracy and unreliability of non-Theranos technology. *See* Dkt. 1181; Dkt. 1156 at 1–11. But as evidenced by testimony in Ms. Holmes' trial, certain parts of this evidence are highly prejudicial on their face. Patient E.T.'s own testimony confirms the prejudicial effect of a positive HIV result. *See* Ex. 51 (Trial Tr. 6758:18) (E.T.'s testimony that receiving the Theranos test result made her "quite emotional at the time").[2]

Patient B.B. As for Patient B.B., three simple things remain clear: (1) the government, as the proponent of Patient B.B., bears the burden of proving that Patient B.B.'s testimony is relevant; (2) the Court's role is to exclude irrelevant and inadmissible testimony under Rules 104(b), 401 and 402; and (3) "[r]elevance cannot be speculative." *See* Dkt. 1155 at 20.

According to his own stated recollection[3], Patient B.B. received four blood tests from Theranos in Arizona in 2015: a fingerstick test on August 11, and three venous draws on August 21, August 27, and December 11. The government argues that it is possible that Patient B.B.'s four tests were run on Theranos' proprietary technology. *See* Dkt. 1181 at 4–5. The government also asserts that all four of Patient B.B.'s tests were inaccurate and unreliable. *Id.* The

[2] Mr. Balwani has moved to exclude emotional testimony from other patients that unfairly plays on jurors' emotions. Dkt. 1156 at 53.

[3] Patient B.B.'s recollection is the only source of confirmation because the government's failure to take appropriate and reasonable steps to preserve the LIS means there is no test report or other data about the test.

government posits scenarios and points to documents that "suggest," "may show," and "support an inference that" that Patient B.B.'s CBC tests were run on Theranos technology. *Id.* at 5. Under the Rules of Evidence, "suggest," "may show," and "support an inference that" are not sufficient. After all, "[r]elevance cannot be speculative." Dkt. 1155 at 20. The government's conjecture cannot confirm that Patient B.B.'s CBC tests were run on Theranos' proprietary fingerstick technology. His testimony must be excluded.

To be clear, Theranos had four CBC test methods approved for use in the clinical laboratory in August 2015—two on unmodified commercial devices (non-Theranos technology) and two on modified commercial devices (Theranos technology):[4]

- Venous sample testing on an unmodified Siemens Advia 2120i (non-Theranos technology) (in use from February 2015 to September 2015). Ex. 53 (TS-0917883) at TS-0917897.
- Venous and fingerstick sample testing on an unmodified Drew 3 (non-Theranos technology) instituted at Theranos' laboratory in late March 2015. Dkt. 1156-2 at 303, 305, 309 (Ex. 12). The dual venous and fingerstick testing capability of this method is an example of why, for the CBC assay, fingerstick testing does not equate with using Theranos' proprietary fingerstick technology: the unmodified Drew 3 could test both fingerstick and venous samples. The government ignores this.
- Fingerstick sample testing on a modified Drew 3 analyzer (Theranos technology) instituted in August 2013. *Id.* at 312, 320. The parties agree that this fingerstick assay was one method used by Theranos at some point in time for CBC testing.
- Fingerstick sample testing on a modified BD LSR Fortessa analyzer (Theranos technology) instituted in September 2013. *Id.* at 329, 334–335 (Ex. 13). The parties

[4] The government's reference to the Advia 2120i as a Theranos modified assay is incorrect. The comparison study to which the government points was comparing Theranos' CBC test on the Drew 3 using its own fingerstick technology *against* the unmodified CellDyn Ruby and Advia 2121 devices. *See* Dkt. 1156-2 at 295 (Ex. 11).

agree that this fingerstick assay is one method used by Theranos at some point in time for CBC testing.

To begin, we do not know where, or on what device, Patient B.B.'s first self-reported fingerstick test in August 2015 was analyzed. If he is correct that he received a fingerstick sample draw, it mostly likely ran on the *unmodified* Drew 3 analyzer put into operation to test fingerstick and venous samples in the Newark lab just a few months earlier, in March 2015. The government simply ignores that Theranos implemented the unmodified CBC test on the Drew 3 for fingerstick and venous samples just months before Patient B.B.'s first test.

But here, that Patient B.B. received a fingerstick test does not resolve the use of Theranos' technology. CBC is different from other assays because it could be and was run on an unmodified commercial fingerstick device (the Drew 3). The government must lay a foundation with more than speculation that Patient B.B.'s first test, though fingerstick, was actually run on Theranos' technology. It cannot do so.

The government then goes even further, speculating that Patient B.B.'s later venous sample tests may have been run on a modified commercial device because the only test report in discovery shows one of the tests was analyzed in its Newark lab where Theranos used its proprietary devices. *See* Dkt. 1181 at 5. To prop up this guesswork, the government cites a November 2014 email by Dr. Rosendorff that was not about CBC testing. *See* Dkt. 1183-4. Again, the government simply chooses to ignore the inconvenient fact that Theranos used unmodified commercial devices it its Newark lab for both venous and fingerstick samples, including for CBC instituted just a few months before B.B.'s testing. To suggest that Theranos "may" have transferred venous blood from larger vacutainers to use with fingerstick analysis for some assay other than CBC is a telling example of the government's rampant speculation on Patient B.B.'s testing. The fact is that the government does not know whether Patient B.B.'s tests were run on Theranos technology. The government cannot lay a foundation that any of B.B.'s CBC tests were performed on Theranos technology by speculating that perhaps this occurred. Otherwise, anyone could lay a foundation for most anything.

The CMS report and cover letter. Finally, the government asserts that Mr. Balwani's request to exclude much of the CMS cover letter and survey report amounts to a motion to reconsider the Court's prior ruling denying Ms. Holmes' motion to exclude this evidence because it is "based upon the same argument[]." *See* Dkt. 1181 at 6.[5] The government quotes nothing from the Holmes litigation on this subject and instead string-cites the briefing, hearings, and order. *See id.* To be sure, Ms. Holmes made a relevance argument to support her motion, but not the same relevance argument. Ms. Holmes argued that the CMS evidence was irrelevant because findings of CLIA violations were not within the scope of the charges, because Theranos received the CMS report after the end of the charged conspiracy to defraud investors, because CMS did not assess whether any tests conducted at Theranos were accurate and reliable, and because the CMS findings would invite the jury to substitute the agency's judgment under the regulations for its own findings on the criminal charges.[6] Dkt. 574 at 3–4, 6; *see also* Dkt. 1191 at 7–10.

Mr. Balwani has elsewhere adopted these arguments. But the issue now before the Court is that most of the CMS findings ***do not*** relate to the accuracy and reliability of Theranos' technology, as alleged in the Indictment. Instead, these findings relate to testing on unmodified commercial devices. This includes the hematology condition-level finding that led to the "immediate jeopardy" determination, as well as documentation, training, and personnel supervisory shortcomings not tied to Theranos' technology. Ms. Holmes never raised that issue.

The government concedes that CMS's "immediate jeopardy" finding stems from its findings related to PT/INR. *See* Dkt. 1181 at 7–8. But the government ignores that the PT/INR testing cited by CMS was run on the Siemens BCS-XP, an unmodified commercial device, and not on Theranos' technology. *See id.* at 7; Dkt. 1157 at 129–31 (Ex. 21). The government does not respond to this fact and instead recites the CMS findings and testimony about the issue as if

[5] The government characterizes Mr. Balwani's motion as one for "reconsideration." But Mr. Balwani was not and could not have been a party to any of the prior motion practice.

[6] When asked under oath about the accuracy and reliability of Theranos' testing, Ms. Bennett testified, "It's not my job to determine whether a result is accurate." Ex. 54 (Bennett Dep. Tr. 185:21–22).

the seriousness of the finding alone renders it relevant to the allegations in the Indictment. *See* Dkt. 1181 at 7.

As it did with HIV, the government then attempts to argue that the Indictment covers PT/INR, an assay run on unmodified commercial devices at the time cited by CMS, by misrepresenting that the Indictment is broader than it is—omitting the specific language in paragraph 16 about "Theranos's technology." *See id.* at 7; *see also* TSI ¶ 16. Then, pointing to the supposed testimony of CMS surveyors Sarah Bennett and Gary Yamamoto, whom they did not bother to call to testify in the Holmes trial, the government posits that an extrapolation can be made based on the findings of one single assay to conclude that there were "systemic errors in Theranos' laboratory." Dkt. 1181 at 8. The government resorts here to basing its claim that findings in the CMS report were mere proxies for unwritten broader issues "[o]n information and belief from the government's interviews of Sarah Bennett …." *Id.*[7] The government uses that entirely speculative proposition to assert that the immediate jeopardy finding expressly and exclusively referring in the report to the non-Theranos PT/INR assay might somehow extend to Theranos' technology as well. *Id.* This is not proper foundation and fails under Rule 104.

The government also claims in passing that the CMS report and cover letter are admissible because they provided notice to Mr. Balwani of the accuracy and reliability issues in the Theranos lab. But the government cannot overcome Mr. Balwani's argument that the report is inadmissible because its findings do not bear on the accuracy and reliability of Theranos technology with its assertion about notice. Notice to Mr. Balwani is relevant only if the issues bore on the accuracy and reliability of Theranos technology. The logic is circular. It fails.

Because the condition-level deficiency and immediate jeopardy findings by CMS stemmed from testing on an unmodified commercial device and not Theranos' proprietary fingerstick technology, the findings are not relevant to the allegations in the Indictment and should be excluded. The same is true for the other findings in the report not tied to Theranos' technology. The Court should adopt Mr. Balwani's proposed redactions. Dkt. 1157 at 84–105 (Exs. 17, 18).

[7] The government interviewed Ms. Bennett seven times.

REPLY IN SUPPORT OF MOTION IN LIMINE NO. 2: DR. DAS

No matter what the government calls him, Dr. Kingshuk Das is an expert witness presenting expert testimony under Federal Rules of Evidence 701 and 702. As Mr. Balwani's motion explained, the government may not offer that testimony where it cannot provide the data underlying Dr. Das' opinions and conclusions. Dkt. 1156 at 16–19. The government does not dispute this point. In its opposition, the government abandons any effort to call Dr. Das as an expert witness and instead argues only that it can classify and call Dr. Das strictly as a lay witness and thereby avoid providing the data. Dkt. 1181 at 11. Then, after engaging in this relabeling exercise, the government says that it can ask Dr. Das to give exactly the same opinions and conclusions without disclosing the data he relied on. This form-over-substance argument is deeply misguided and should be rejected.

A. An Expert Witness Cannot Testify Without Disclosure of the Data Underlying His Opinions and Conclusions

To begin, the government does not dispute the central legal plank of Mr. Balwani's motion: An expert must disclose his or her data.[8] That is precisely what both parties have done for their other potential experts. *See* Ex. 52 (Master Report) at 43–50 (App'x B); Dkt. 1158 at 24–26 (Mr. Sonnier); Dkt. 1179-2 at 19–42 (Mr. Oustalniol); *id.* at 44–48 (Mr. Weingust). Because the data Dr. Das analyzed to reach his opinions and conclusions has never been disclosed, all testimony from Dr. Das that crosses the line into expert territory must be excluded.

B. The Government Makes No Effort to Provide the Data Because It Cannot

The government has no meaningful response about the missing data. To the extent the data came from Theranos' LIS, the government does not have it, because remarkably it failed to take the necessary steps to obtain the central scientific evidence in a case alleging scientific fraud. In fact, the government's own support staff advised the prosecution team to encourage Theranos "to consider handing over its physical SQL server and [to] set[] it up in a workroom" in *October*

[8] *See* Dkt. 1156 at 17 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Donahue v. Barnhart*, 279 F.3d 441, 446 (7th Cir. 2002); *United States v. Sheppard*, No. 5:17-CR-00026, 2021 WL 1700356, at *5 (W.D. Ky. Apr. 29, 2021); *Kriedler v. Pixler*, No. C06-0697RSL, 2010 WL 1507888, at *1–2 (W.D. Wash. Apr. 14, 2010)).

2018—in other words, precisely what Richard Sonnier's unrebutted expert testimony explained should have been done. Ex. 56 (Oct. 29, 2020 *Brady* letter) at 22; Dkt. 1158.[9] The government now tries to sidestep the issue by claiming that some data may have been sourced elsewhere or that Dr. Das may not have relied "directly" on LIS data. Dkt. 1181 at 11. That is extremely doubtful given that the LIS was the central repository of Theranos' laboratory data, including "all patient test results and all QC data," as the government has conceded. Dkt. 669 at 1. But even if the data came from outside LIS, the point remains: The government still has not identified or disclosed the data that Dr. Das relied on. *See* Dkt. 1181 at 11. Even the government seems to acknowledge that it cannot present an expert witness to testify about the ultimate issue of falsity in a wire fraud case based on secret data and ask the Court, jury, and defense to just take his word for it. *See* Dkt. 1156 at 17.

C. The Vast Bulk of Dr. Das' Testimony Is Expert Testimony

Most of Dr. Das' testimony is expert testimony, but the government ignores this in its opposition. *See* Dkt. 1156 at 13; Dkt. 1181 at 9–10. Rather than address Dr. Das' actual testimony at Ms. Holmes' trial, the government instead goes back to 302s and other materials before the testimony. *See* Dkt. 1181 at 9–11. But looking at Dr. Das' trial testimony, the government fails to answer how Dr. Das could explain to the jury the statistical concept of standard deviation and the "two standard deviation" rule he applied without employing specialized knowledge. *See* Ex. 51 (11/9/21 Trial Tr. 5817:2–16, 5820:2–24, 5831:11–18, 5847:7–5848:12). So too with explanations of quality control standards, analysis of the clinical suitability of the Edison device, and use of technical expertise to explain Levey-Jennings charts and reach conclusions about the

[9] Repeating the same thing again like a mantra does not make it true: The government asserts again that it "was led to believe that it had a viable copy of all the information stored in the LIS, obviating any need to obtain the original copy of the database or seek additional hardware." Dkt. 1181 at 13. As a result, the government asserts, it need not "have taken additional steps to obtain the LIS database." *Id.* This argument ignores advice the government received from both Theranos' counsel and the government's own technology experts that a copy of the LIS database would be insufficient and that more needed to be done to obtain the data. *See* Ex. 55 (May 23, 2018 email, Romeo to Taylor et al.); Ex. 56 (Oct. 29, 2020 *Brady* letter) at 22. Had the government secured the servers or hard drives before or long after August 31, 2018, it would have obtained the LIS with no need for an encryption key. Dkt. 1158 at 7–9 (Sonnier Decl.). The government's opposition does not even mention, much less rebut, the expert opinion on the loss of the LIS data offered with Mr. Balwani's motion. *See* Dkt. 1156 at 15–16

validity of CMS's findings. In an exhibit filed alongside this reply, Mr. Balwani catalogs many instances when Dr. Das crossed the line from lay to expert testimony. *See* Ex. 57. Taken as a whole, Dr. Das' trial testimony was permeated with specialized knowledge and expert opinion. The issues the government wants Dr. Das to speak to in Mr. Balwani's case are the same.

1. These Issues Have Not Already Been Decided

The government is wrong that whether all of Dr. Das' testimony is expert or percipient has already been decided. Dkt. 1181 at 9–10. The government also presents an inaccurate recitation of what occurred at Ms. Holmes' trial and the Court's ruling about Dr. Das before that trial started.

The government claims that Dr. Das' testimony was "admitted either without objection or over objection" at Ms. Holmes' trial. Dkt. 1181 at 10. Contrary to the government's assertions, there were no objections over the examples described in Mr. Balwani's motion, as shown in the chart accompanying this motion. There were only a handful of objections during Dr. Das' direct examination in any event. *See* Ex. 51 (11/9/21 Trial Tr. 5818:16–20, 5819:14–18, 5821:8–10, 5854:2-5, 5855:17–20, 5856:3–4, 5856:20–21).[10] As a result, the Court did not have a chance to rule on the vast majority of Dr. Das' expert testimony. One defendant's decision not to object does not determine anything for a future defendant; it just means that the issue has not yet been addressed.[11]

The government is also wrong to suggest that the Court has already decided all these issues in the context of the Holmes trial. *See* Dkt. 1181 at 9–10. First, contrary to the government's representation, the Court did not deny Ms. Holmes' pretrial motion on Dr. Das. *See* Dkt. 1181 at 8. Instead, the Court deferred any decision until Dr. Das testified. Dkt. 989 at 4. The Court's ruling specifically put the "parties … on notice" that Dr. Das' testimony "would move …

[10] A number of those objections were sustained. *Id.* (11/9/21 Trial Tr. 5818:16–20, 5819:14–18, 5854:2–5, 5855:17–20). Some of the testimony that was allowed over defense objection is inadmissible for other reasons Mr. Balwani has put forward: For example, testimony about issues with the PT/INR assay is inadmissible because it does not go to accuracy and reliability of Theranos technology as charged in the Third Superseding Indictment. *See* Dkt. 1156 at 1–11; *supra* at 1–10.

[11] Mr. Balwani is not criticizing Ms. Holmes' counsel, who are entitled to make their own trial decisions.

from percipient to expert" if it involved scientific matters "that would require specialized knowledge to understand and interpret." Dkt. 989 at 4. Although the Court noted that such expert topics "include[ed]" Dr. Das' Six Sigma analysis, the Court cited this merely as an example and did not rule that the Six Sigma analysis was the only area that crossed the expert line. On the contrary, the Court instructed that, should other expert topics arise at trial, the defense "may object at that time." *Id.* As the Court predicted, the government sought to veer into expert territory at trial. *E.g.*, Ex. 51 (11/9/21 Trial Tr. 5819:17–18) ("I think you're asking for an opinion that falls under 702 the way the question is formed, so I'll sustain the objection."). Through this motion, Mr. Balwani now squarely presents the expert-testimony issue not ultimately adjudicated in the Holmes trial. Moreover, unlike in Ms. Holmes' case where the parties and the Court were looking pre-trial at the expert testimony issues based only on anticipated testimony, now Dr. Das' testimony is already in the record, so there is no need to defer. All the testimony identified in Exhibit 57 crosses into the realm of expert testimony and must be excluded as a result.

2. The Government Misunderstands the Line Dividing Lay and Expert Testimony

The difference between lay and expert testimony is whether it relies on "scientific, technical, or other specialized knowledge." Fed. R. Evid. 701(c); *accord* Fed. R. Evid. 702(a). Each of the examples above and in the attached Exhibit 57 does. That is presumably why the government disclosed Dr. Das as potentially offering expert testimony within the scope of Rule 702, although it now apparently disclaims that characterization. *See* Dkt. 1179-2 at 66–67 (Ex. 48). Even Dr. Das conceded that his analyses of the Theranos data were "pretty sophisticated," "pretty technical," and "not something that in [Dr. Das'] view someone without knowledge and training would be in a position to do." Ex. 51 (11/10/21 Trial Tr. 5937:14, 21–22, 5953:2–3). That is plainly expert testimony under Rule 702.[12]

[12] The government's example about a hypothetical Chief Financial Officer is misplaced. Dkt. 1181 at 11. Adding numbers together is hardly the same as reviewing reams of QC and patient data and expressing an opinion based on experience and training as a clinical pathologist about what the data may mean. *See also infra* at 22 (discussing *United States v. Chen*).

As explained in Mr. Balwani's motion on lay and expert testimony, the government should not be permitted to avoid this conclusion by arguing that Dr. Das is merely a percipient witness. *See* Dkt. 1156 at 36–39; *infra* at 21–23. Testimony describing conclusions reached through expert means *is* expert testimony. Here, Dr. Das conducted a backward-looking analysis of Theranos data using technical and scientific methods. He applied those methods and reached conclusions—methods and conclusions he now intends to present to the jury, based on data that is no longer available for the Court to assess under Rule 702(b) and (d) and for defense counsel to use during cross-examination. If there were still any doubt on this score, the government dispelled it the day before this filing by confirming again that Dr. Das had applied specialized knowledge to draw conclusions from data it has never identified:

> [D]r. Das did his own independent analysis, reviewed a broader universe of data than had been provided to CMS, and concluded that the deficiencies identified in the CMS report were only a "representative" sample of the actual deficiencies within Theranos' Newark laboratory. Indeed, Dr. Das found in his internal review that there were multiple instances where Theranos reported patient results in 2014 and 2015 *after* Theranos' proprietary blood analyzer (the Edison) had failed quality control. Dr. Das reviewed Theranos' own quality control data from 2014 and 2015 [and] found "a possible patient impact for every test reported" that was performed on the Edison and thus urged Defendant to void all tests run on Theranos' proprietary blood analyzer and for a few other assays. Dr. Das testified that he "found these [Theranos proprietary] instruments to be unsuitable for clinical use."

Dkt. 1192 at 4–5 (second set of brackets in original) (citations omitted). If that is not expert testimony, then nothing is.

Having to take an expert's word for it is not our criminal-justice system. The government appears to concede that, without disclosing all the underlying data to defense counsel, the government cannot call Dr. Das as an expert. But the government cannot now circumvent Rule 702 and elicit those expert opinions by simply relabeling him as a percipient witness.

D. Conclusion

For these reasons, the Court should exclude any and all expert testimony that the government offers from Dr. Das. The line between expert and percipient witness must be drawn based on the substance and not on the label the government attaches to evade the rules.

REPLY IN SUPPORT OF MOTION IN LIMINE NO. 3: VOIDING TEST RESULTS

The government contends that a regulation required Theranos to void the results of tests run on its Edison device. But the sworn testimony of two CMS officials disclaims any such requirement. Because binding precedent mandates deference to this view in the face of uncertainty over the regulation's meaning, Theranos' decision to void the test results was voluntary, and thus inadmissible at trial under Federal Rule of Evidence 407. Evidence on voiding is also inadmissible under Rule 403 based on reasoning in a prior ruling of the Court that the government casts aside.

The government asserts in opposition that Mr. Balwani "raises essentially the same arguments" in his motion that Ms. Holmes did in litigating this issue. *See* Dkt. 1181 at 14. Not so. In fact, the government fails to respond to—and thus concedes—most of Mr. Balwani's arguments. As for the arguments the government chooses to address, the opposition is meritless. The Court should thus grant Mr. Balwani's motion and exclude evidence of Theranos' voiding test results.

Rule 407. To start, the government fails to contest a host of Mr. Balwani's arguments never raised by Ms. Holmes. The government does not dispute that whether "Theranos had a legal obligation to void tests in response to deficiencies identified by CMS … is a question of law." Dkt. 1156 at 23. Nor does the government engage with the Court's earlier reasoning that testimony on legal conclusions is improper. *See* Dkt. 798 at 71 (citing *SEC v. Capital Consultant, LLC*, 397 F.3d 733, 749 (9th Cir. 2005)). Similarly absent from the government's opposition is any contention that the CMS officials' sworn deposition testimony is not the kind of authority to which courts must defer under *Auer v. Robbins*, 519 U.S. 452, 461 (1997). Instead, the government tries to sidestep this principle by calling *Auer* deference "beside the point." Dkt. 1181 at 16.

The government is wrong. It is precisely in these circumstances that courts must conform their interpretations to those of the regulator. *See* Dkt. 1156 at 25 (citing cases). Both CMS surveyors who inspected Theranos testified under oath, and while represented by agency counsel, that CMS neither asked nor required Theranos to void its Edison test results. *See* Dkt. 1157

(Exs. 34–36). The government has not identified—and cannot identify—one word in CMS's authoritative interpretative guidelines or administrative decisions under the CLIA program that discusses voiding test results or mandates such a step. *See* Dkt. 1156 at 24. This sort of uncertainty over the application of 42 C.F.R. § 493.1291(k)—the regulation the government claims obligated Theranos to void the results of its Edison tests—is exactly what *Auer* deference aims to resolve.

Rather than address this principle, the government deflects. It cites Ms. Bennett's testimony that once CMS has identified a deficiency, it is for the lab director to determine the appropriate corrective action. *See* Dkt. 1181 at 15. But leaving it up to the lab director, by definition, means that the particular action taken is voluntary: the lab director could decide to void all the tests, to increase training, or to take a host of other voluntary corrective actions. The government also acknowledges Mr. Yamamoto's testimony—which just strengthens Mr. Balwani's position—that a typical remedial measure for a deficiency would entail alerting patients to potential issues with their tests and advising the patients "that they may want to get retested." *Id.* (quoting Dkt. 1157 at 328). But the argument that because Theranos had to do *something* in response to CMS's deficiency findings meant that it had to take the specific step of voiding all Edison test results lacks support in the facts and the law.

Starting with the facts, the government ignores that CMS itself cited 42 C.F.R. § 493.1291(k) in its deficiency findings, and importantly, applied it only to the PT/INR test—an assay run on Siemens BCS XP, an unmodified commercial device—not to the Edison or any other Theranos technology. *See* Dkt. 1156 at 24. In fact, no correspondence or patient impact assessments from CMS, Dr. Das, or anyone else ever linked § 493.1291(k) to the Edison test results or to any other Theranos technology. And Dr. Das never identified that provision (or any other) as the basis for Theranos' purported requirement to void results until the government suggested it to him. *See id.* at 26.[13]

[13] The opposition fails to respond to the argument that the foundation the government laid for Dr. Das' conclusion in Ms. Holmes' trial was improper because it turned on a question that was both leading and compound. Dkt. 1156 at 26. Nor has the government challenged Mr. Balwani's request for a Rule 104(c) hearing outside the jury's presence to address the issue. *See id.*

As for the law, nothing supports the government's inference that, because Theranos had to address CMS' findings *somehow*, choosing—from among many options—to void tests was itself involuntary. The "voluntariness" exception to Rule 407 appears nowhere in the Rule's language or advisory committee notes. It is a creature of case law, so the government should provide a case endorsing its understanding. It fails to do so. To the contrary, the government's theory runs headlong into the Fourth Circuit's decision in *Werner v. Upjohn Co.*, 628 F.2d 848, 859–60 (4th Cir. 1980). There, the court rejected the plaintiff's argument that the FDA required a change in the warning label for a particular drug, making the new warning involuntary and thus admissible under Rule 407. As the court reasoned, "[t]he FDA can require that a warning be changed, but this does not tell the whole story. [The agency] also relies on voluntary compliance and compromise in determining the content of warnings …" *Id.* at 859. The court did not read the FDA's regulatory power in *Werner* "as in conflict with the protective policy of Rule 407" because the agency's policies, like Rule 407, "encourage early unilateral action." *Id.* at 860. So too here. As in *Werner*, CMS required Theranos to do something. It did not mandate the voiding of test results. Theranos determined that voiding was the best way to proceed for the company regarding tests that had occurred years before. Allowing that decision to be used as a cudgel will undermine the goal of encouraging remedial action that Rule 407 promotes.

Rule 407 thus bars admission of any evidence of Theranos' voiding the Edison test results.

Rule 403. One would not know from the opposition that the Court already found compelling Ms. Holmes' arguments on voiding under Rule 403. Specifically, the Court expressed concern that evidence on voiding risked confusing the issues because Theranos' lab practices were not at issue in the Indictment, risked a mini-trial on the regulatory backdrop for CMS's actions, and raised the specter of unfair prejudice because the decision to void tests in 2016 "is not probative of [the defendant's] intent during … the years that are the subject of the indictment." Dkt. 798 at 37–38. The government ignores these concerns, giving short shrift to its obligation to "clearly tie[] the events in 2016 to the charged conduct." *Id.* at 38.

The government focuses on Mr. Balwani's involvement in hiring Dr. Das—an exculpatory fact—and Dr. Das' impermissible expert analysis during his employment. *See* Dkt. 1181 at 17–

18. It also notes a meeting Dr. Das had with Ms. Holmes' and Mr. Balwani where he received "push back" on his concerns about the Edison device. *Id.* at 18. But the government omits that it was Ms. Holmes who pushed back, and cannot escape Dr. Das' testimony that he reported directly to Ms. Holmes and had minimal contact with Mr. Balwani. *See id.*; *see also* Dkts. 1133 at 9, 1156 at 28. Nor is the government's claim that Dr. Das' agreed with CMS's conclusions convincing: as Mr. Balwani explains in his motion to exclude evidence related to unmodified commercial machines, most of CMS's deficiency findings had nothing to do with Theranos' technology. They thus had nothing to do with the charged conduct. None of these proffered events "clearly ties the events in 2016 to the charged conduct," i.e., to representations made to patients and investors before 2016. Dkt. 798 at 38.

These facts are far weaker foundation than those the government pointed to in Ms. Holmes' trial to satisfy the Court's demand to show clear ties between voiding and the charged conduct. *Cf.* Dkt. 1133 at 2–3, 9–10. There, the government emphasized Dr. Das' "regular meetings" with Ms. Holmes, Ms. Holmes' noting her conduct after receiving the CMS report in her opening statement, and Ms. Holmes' introduction, sometimes over the government's objections, of her own conduct in 2016 and beyond. *See id.* The same reasoning does not apply to Mr. Balwani.

Thus, the lack of clear ties between the voiding and the charged conduct is an independent basis to exclude evidence of voiding.

REPLY IN SUPPORT OF MOTION IN LIMINE NO. 4: COCONSPIRATOR STATEMENTS

The government urges the Court to deny or defer ruling on Mr. Balwani's motion to exclude alleged coconspirator statements made outside the time of any conceivable conspiracies because, it claims, it is unlikely to rely exclusively on Rule 801(d)(2)(E) to admit any such statements, and if it does, it will be able to establish a then-existing conspiracy. Dkt. 1181 at 19. Neither argument justifies denying or deferring Mr. Balwani's motion. Because the government has neither alleged nor argued—and in fact has recently disclaimed—the existence of any conspiracy before September 2009 or after mid-2016, the Court should preclude the government

from relying on Rule 801(d)(2)(E) outside that window.

The government identifies no evidence suggesting a conspiracy existed before September 2009 or after mid-2016. It notes the Court's observation in the Holmes trial that "the evidence that has come in does establish … a *prima facie* case" that a conspiracy existed. Dkt. 1181 at 19; *see* Ex. 51 (11/02/21 Trial Tr. 5013:07–10). But the Court's statement was limited to "the charging period" (2010 through 2016), *Id.* 5015:01–05, and Mr. Balwani seeks to exclude coconspirator statements made *outside* that window.[14]

For those statements, the government does not even try to argue that Rule 801(d)(2)(E) applies. The government claims that Ms. Holmes' pre-2009 statements will "likely be offered for the effect on the investor's state of mind," not for their truth. Dkt. 1181 at 19–20. While that may be a non-hearsay use, these statements are inadmissible for a more fundamental reason: In the government's words, "actions … taken by Theranos under different corporate leadership" are generally "not relevant to [Mr. Balwani's] participation in the two schemes to defraud" and will likely "confuse and mislead the jury." Dkt. 1155 at 6. As for statements made by Ms. Holmes after Mr. Balwani left Theranos, the government agrees they "are largely irrelevant." Dkt. 1181 at 20; Dkt. 1155 at 6.[15] And, despite its recent disclosure to the contrary, Dkt. 1156 at 31, the government now disclaims any intention to offer Ms. Holmes' 2016 and 2017 statements to CNN and the SEC. Dkt. 1181 at 20.[16]

Although the government has generally disclaimed the relevance of events that occurred

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[14] Although the indictment describes the later conspiracy—to defraud patients—as ending at an unspecified time in 2016, the government has since conceded that events at Theranos after Mr. Balwani left in July 2016 are largely "not relevant to [his] participation in the two schemes to defraud." Dkts. 1155 at 6, 1181 at 20. *But see infra* n.15.

[15] As Mr. Balwani has explained elsewhere, evidence of actions taken by Theranos (or Theranos executives) after Mr. Balwani's resignation "may be relevant if the defense shows that Mr. Balwani's 'input' or 'influence[]' 'affected' the company's actions after his departure," or if "it bears on events that occurred while Mr. Balwani worked at Theranos." Dkt. 1179 at 5. But that does not justify introducing otherwise hearsay statements made after his resignation under Rule 801(d)(2)(E). *See* Dkt. 1156 at 33–35.

[16] The government chides Mr. Balwani for requesting "advance notice of potential coconspirator statements the government may offer at his trial." Dkt. 1181 at 19. But as the Court has recognized, such disclosures are required. *See* Local Rule 16-1(c)(4); Ex. 51 (11/02/21 Trial Tr. 5013:16–5015:21).

when Mr. Balwani was not "associated with Theranos," Dkt. 1155 at 6, it describes his motion to exclude Rule 801(d)(2)(E) statements before and after his tenure at Theranos as "premature," and urges the Court to deny or defer it because any alleged coconspirator statements "will be admissible under alternative theories as in the *Holmes* case." Dkt. 1181 at 18–19. That is no reason to disregard Mr. Balwani's motion. The government has invoked Rule 801(d)(2)(E) in Ms. Holmes' trial several times. *See* Ex 51 (9/22/21 Trial Tr. 1511:02–03; 10/13/21 Trial Tr. 3406:22; 11/02/21 Trial Tr. 5001:21). And even if the government might rely on other theories of admissibility, the point of a motion in limine is "to resolve issues which would otherwise clutter up the trial." Dkt. 798 at 4 (quotation omitted). Granting Mr. Balwani's motion would clarify that the government cannot rely on Rule 801(d)(2)(E) to introduce coconspirator statements made outside the relevant period.

Since the government does not contend that either alleged conspiracy began before September 2009 or continued after mid-2016, the Court should grant Mr. Balwani's motion to exclude any statement made outside that period offered under Rule 801(d)(2)(E).

REPLY IN SUPPORT OF MOTION IN LIMINE NO. 5: IMPROPER EXPERT OPINION

Mr. Balwani asks the Court to police the line between permissible lay opinion and testimony that a jury may hear only from an expert. In Ms. Holmes' trial, the testimony of entry-level Theranos lab employee Erika Cheung often transgressed this line. In opposing the motion, the government defends the admissibility of a host of statements that Mr. Balwani's motion does not challenge—largely ignoring the ones he does. The government also fails to cite—much less distinguish—a single authority offered by Mr. Balwani. And the government tries to defend Ms. Cheung's over-the-line testimony by analogizing to percipient testimony from Adam Rosendorff, while ignoring the testimony from Dr. Rosendorff that could be admissible only if he is qualified as an expert at Mr. Balwani's trial. These arguments lack merit, and the Court should grant Mr. Balwani's motion.

To begin, Mr. Balwani challenges the admissibility of testimony that rests on the specialized knowledge that requires qualification as an expert for admission. Ms. Cheung testified, for instance, that a "normal lab" would see "less than [a] 1 percent" test failure rate and

that the purported failure rate in Theranos' lab was therefore concerning. *See* Dkt. 1156-2 at 19. (Ex. 1). She next explained the medical significance of an out-of-range Vitamin D test. *Id.* at 18. She also opined on the cause of quality control failures—that the Edison device was not working. *Id.* at 17. These opinions about industry standards, medical interpretations, and guesses about the causes of purported technological failures are classic expert testimony impermissible for a witness who cannot be qualified as an expert. *See, e.g.*, *United States v. Urena*, 659 F.3d 903, 908 (9th Cir. 2011); *Jerden v. Amstutz*, 430 F.3d 1231, 1239–40 (9th Cir. 2005). Even the government disclaims any intent to elicit testimony from Ms. Cheung on "industry standards or the performance of labs other than Theranos." Dkt. 1181 at 22. And it nowhere tries to distinguish the case law cited by Mr. Balwani.

The only authority the government cites is *United States v. Chen*, which, the government claims, rejected a contention "similar" to Mr. Balwani's. *See id.* at 22 (citing Case No. 17-cr-00603-BLF-1, 2021 WL 2662116, at *9–10 (N.D. Cal. June 29, 2021)). But the challenge in *Chen* in no way resembles Mr. Balwani's objection. There, the court allowed testimony from employees about "whether certain technical information was treated as confidential; how [the company] stored CAD drawings and bills of material … in a secure, confidential database; and how [the company] required employees not to share CAD drawings with third parties without a non-disclosure agreement." *Chen*, 2021 WL 2662116, at *9. Simply describing firsthand experiences with company security policies or describing one's experience "extract[ing] emails … from Defendants' work computers" is different from telling the jury the typical error rate in other labs or that quality controls failed because a technology was flawed. *See United States v. Conn*, 297 F.3d 548, 554 (7th Cir. 2002) ("Lay opinion testimony most often takes the form of a summary of first-hand sensory observations.").

Nor can the government salvage Ms. Cheung's impermissible expert opinion by relying on the Court's narrow pretrial rulings on Dr. Rosendorff's testimony in the Holmes case. First, the Court never blessed lay opinion about the ultimate cause of purported testing failures or industry standards. *See* Dkt. 798 at 75–78. In fact, the Court observed that because Dr. Rosendorff's testimony "will not be introduced to argue that Theranos' [practices] were

violating industry standards, the introduction of a scientific basis and methodology pursuant to Rule 702 is not needed." *Id.* at 77. Instead, the Court ruled only that it would not "issue a blanket exclusion of evidence relating to" Theranos' reference ranges, multiplexing method, or information withheld from doctors and patients. *Id.* at 76–78. The Court delineated potential evidence that would not require expert testimony—for example, what suggestions Dr. Rosendorff made to the defendants and their reactions, what information was disclosed to doctors and patients, and "what multiplexing entailed." Those require no specialized knowledge, unlike Ms. Cheung's challenged statements here. Second, the objection to Ms. Cheung's testimony cannot be cured by offering her as an expert—she does not have sufficient education or experience to be qualified as an expert in this area. For Dr. Rosendorff, by contrast, the government has identified him as a potential expert and may offer him as one at trial. If the government does not do so, Mr. Balwani may raise any specific objections to improper expert opinion if the government tries to elicit it.

Because the government neither addresses Mr. Balwani's arguments nor counters his proffered authorities, the Court should exclude the challenged testimony of Ms. Cheung.

REPLY IN SUPPORT OF MOTION IN LIMINE NO. 6: TEXT MESSAGES

Mr. Balwani has argued that the October 16, 2015 text string containing the inflammatory terms "the death and sex thing," "murder," and "filth" should be excluded under Rules 401–403. Dkt. 1156 at 40–44. In opposition, the government asks the Court to deny or defer ruling on Mr. Balwani's motion because, it claims, the texts are relevant, not unfairly prejudicial, and can be selectively redacted to avoid any prejudice. It is wrong on all fronts.

First, the government refers to the evidence Mr. Balwani seeks to exclude as "a string of text messages in which Defendant Balwani and co-Defendant Holmes discuss their plan to discourage the *Wall Street Journal* from publishing a negative story about Theranos." Dkt. 1181 at 23. The government's theory of relevance turns on speculation and mischaracterizes the text string at issue. To start, the text string occurs *after* the publication of the *Wall Street Journal* article. *See* Dkt. 1179-2 at 187 (Ex. 50) (noting that *Wall Street Journal* article "is out" on October 15, 2015). To show that the text string is relevant to Mr. Balwani's knowledge and

intent, the government points to an email (Trial Exhibit 5704) that Ms. Holmes sent Rupert Murdoch on September 8, 2015—more than a month before the challenged text string—supposedly "in an effort to encourage Mr. Murdoch to intervene in the *Wall Street Journal*'s plan to publish a negative story about Theranos." Dkt. 1181 at 23; *see* Ex. 58 (Trial Exhibit 5704). Based on this exhibit, the government claims that the text string "show[s] Defendant Balwani knew about (and approved of) co-Defendant Holmes' plan to contact Rupert Murdoch for the purpose of killing the *Wall Street Journal*'s impending negative article." *Id.* at 24.[17]

The government fails to explain how texts about whether to share "the death and sex thing" with Mr. Murdoch in October 2015 show that Mr. Balwani knew about—let alone approved—Ms. Holmes' email to Mr. Murdoch a month earlier. And because Ms. Holmes and Mr. Balwani exchanged these texts the day after the *Wall Street Journal* published the negative article, the article was not "impending" as the government claims. Dkt. 1181 at 24.

The government also fails to rebut Mr. Balwani's argument that the references to "death," "sex," "murder," and "filth" are unfairly prejudicial, confusing, and misleading in a wire-fraud case. *See* Fed. R. Evid. 403. If the texts are admitted, the jury will no doubt wonder why the defendants were texting about "murder," "sex," and "death" between themselves, let alone in drafting a communication to Mr. Murdoch. The Rule 403 risks posed by such sensational and unseemly references untethered to the charges are self-evident.

The government sheds no light on what any of these unadorned references mean. Instead, it speculates—with no support or citation—that "those references relate to co-Defendant Holmes' experiences and not this Defendant." Dkt. 1181 at 24. Putting aside the government's speculation, even if those references related only to Ms. Holmes, that would make them even less relevant to Mr. Balwani. If the texts about "death" and "sex" relate only to Ms. Holmes, then they do not bear on Mr. Balwani's "knowledge and intent." *Id.* The texts cannot relate to Mr. Balwani for purposes of Rule 401, but not for purposes of Rule 403. The government cannot have it both

[17] It is worth noting that Exhibit 58 came into evidence during the cross-examination of Ms. Holmes, not through a government witness. Ex. 51 (11/30/21 Trial Tr. 8000:20–24). Even if these texts could be construed as relevant, Mr. Balwani reserves his right to object if the government cannot lay a proper foundation for Exhibit 58.

ways. Nor can the government rely on Ms. Holmes' choice "not to object to [the] admission" of these texts as a reason to ignore Mr. Balwani's arguments. *Id.* Mr. Balwani obviously is not bound by Ms. Holmes' trial decisions; whether she objected to the introduction of these texts does not affect his case.

Finally, the government argues that the Court could redact the references to "sex" and "murder" to prevent any prejudice. *Id.* Redactions are the very least that is required here, but the government's proposed redactions would not cure the Rule 403 risk of confusion. They would leave unexplained references to the defendants' "personal life," "death," and "filth" that "people on Twitter will assume" means "there is something there" to be uncovered. Dkt. 1156 at 41. Redacting some words in this confusing conversation would only invite the jury to speculate about the missing information in a prejudicial "Mad Libs" exercise. *See United States v. Hoac*, 990 F.2d 1099, 1107 (9th Cir. 1993) (redactions risk "invit[ing] the jury to 'fill in the blanks'"). Any negligible probative value of this evidence cannot justify admitting even a redacted version. *See United States v. Hitt*, 981 F.2d 422, 424 (9th Cir. 1992) ("Where the evidence is of very slight … probative value, it's an abuse of discretion to admit it if there's even a modest likelihood of unfair prejudice or … misleading the jury."). It should be excluded entirely.[18]

REPLY IN SUPPORT OF MOTION IN LIMINE NO. 7: LICENSE PLATE

The government does not oppose Mr. Balwani's request to exclude evidence of his personalized license plate and the car to which it was attached. The Court should thus grant the motion.

REPLY IN SUPPORT OF MOTION IN LIMINE NO. 8: PRIOR RULINGS

Mr. Balwani addresses below the government's argument on seven issues the Court decided in the Holmes trial.

Wealth, Spending, and Lifestyle. The government suggests no reason for the Court to alter its prior ruling precluding the government from offering evidence on wealth and spending

[18] If the Court denies Mr. Balwani's motion, he expects the government to stand by its assertion that it will "provide advanced notice to Defendant before it admits this thread." Dkt. 1181 at 24.

flowing from Mr. Balwani's work at Theranos. *See* Dkt. 798 at 8–9. The government does not respond to Mr. Balwani's contention that introducing evidence of Ms. Holmes' spending would be especially prejudicial, *see* Dkt. 1156 at 51 & n.23, so the Court should bar this evidence. Last, the government offers no reasoning or case law supporting its claim that Mr. Balwani's use of evidence of his pre-Theranos wealth would appeal to class prejudice in the same way as a suggestion by the government that specific purchase details owing to Mr. Balwani's work at Theranos show a motive to commit fraud. *See* Dkt. 1181 at 26. The government's argument is instead a transparent effort to bar admissible evidence undermining any alleged intent to defraud.

Certain Settlements. Mr. Balwani addresses the only argument in the government's opposition on this issue in his reply above supporting his motion to exclude evidence of voiding test results.

Certain News Articles. The government asks the Court to "remain open to reconsidering whether to admit some" articles—including the October 2015 *Wall Street Journal* article—to give "context" to the jury. Dkt. 1181 at 27. This argument—unsupported by citation to any authority—ignores the Court's reasoning that these hearsay materials can be referenced for context in the same way they were in the Holmes trial. In other words, it is enough to refer to the fact of an article, perhaps noting that it included negative coverage of Theranos. But nothing can overcome the overwhelming prejudice of allowing rank hearsay like the *Wall Street Journal* article to be shown when many of its secondhand claims are the same ones the jury will be addressing in deliberations. That would just invite the jurors to substitute the *Wall Street Journal*'s findings for their own, with no chance for Mr. Balwani to challenge those claims.

Customer Impact Evidence. The government offers no real challenge to the Court's adopting the parameters it set for the Holmes trial by excluding "emotional, graphic, or otherwise inflammatory evidence relating to the impact or potential impact on customers of inaccurate test results." Dkt. 798 at 52; *see* Dkts. 1156 at 53, 1181 at 27. But the parties disagree on whether the Court's ruling requires excluding certain testimony by Drs. Zachman and Rosendorff that the government introduced during Ms. Holmes' trial. *See* Dkt. 1156 at 53 (quoting this testimony). The government argues that it honored the Court's prior order because this testimony "properly

fall[s] within the 'next steps' category of testimony that the Court permitted" and does not veer into "emotional, graphic, or otherwise inflammatory topics." Dkt. 1181 at 27–28. This argument is belied by a plain reading of the witnesses' testimony.

Dr. Zachman testified about her patient B.G.'s "surprise" and "sadness" at receiving a Theranos hCG result suggesting she might be experiencing her fourth miscarriage. Dkt. 1156-2 at 25 (Ex. 1). B.G.'s surprise and sadness is classic emotional evidence that lacks probative value and is unfairly prejudicial. Dkt. 1156 at 53. So too for Dr. Zachman's testimony that "as a woman" she felt "empath[y]" for B.G.'s "very impactful" experience. *Id.* The government's argument that this testimony—about surprise, sadness, empathy, and impact—relates to "next steps" rather than emotions strains credulity.

Dr. Zachman testified that she and B.G. discussed ways to potentially terminate the pregnancy. This falls within the category of excluded impact evidence. *See* Dkt. 798 at 52. It is not testimony about "next steps," because B.G. never terminated her pregnancy. And testimony about discussing terminating a pregnancy after multiple miscarriages is extremely prejudicial and has no probative value since she did not take those steps. The next steps B.G. actually took—taking more hCG tests—informed her and Dr. Zachman that B.G.'s pregnancy was viable, and she carried the baby to term. Dkt. 1156-2 at 25; Ex. 51 (9/21/21 Trial Tr. 1400:8–22).
Dr. Rosendorff's testimony about the hypothetical impact of "an abnormally high potassium result" falls into this same category of excluded evidence. Dkt. 1156 at 53.

The government resists exclusion because "there is no guarantee that the witnesses will testify in exactly the same manner at both trials." Dkt. 1181 at 27. This assertion ignores the purpose of pretrial evidentiary rulings and the government's obligation to instruct its witnesses about them. The Court should adopt its prior ruling and exclude the challenged testimony.

Alleged Blaming and Vilifying of Competing Companies and Journalists. The government offers no basis for the Court to depart from its prior ruling (1) excluding the profane chants allegedly led by the defendants, and (2) deferring ruling on the admissibility of the "statements to Walgreens employees and the all-hands meeting statements." Dkts. 798 at 68–70, 1156 at 53–54, 1181 at 28. Part of that ruling, which the government omits, is that the latter

statements should be admitted only if the government proves their falsity, *see* Local Rule 16-1(c)(3), and shows "why statements about potential sabotage by Theranos competitors tends to shed any light on investor fraud." Dkt. 798 at 70 ("The Court declines the Government's invitation to allow the Government to escape its Criminal Local Rule 16-1(c)(3) obligations ….").

While Mr. Balwani maintains that all this evidence should be excluded, *see* Dkt. 1156 at 53, the Court should, at a minimum, adopt all of its prior ruling, including requiring the government to comply with Local Rule 16-1(c)(3) and to tie the Walgreens and all-hands meeting statements to the charges before those statements are admitted.

Tests Not Identified in the Bill of Particulars. The Court need not reconsider its prior ruling barring evidence on the accuracy and reliability of tests not listed in the Bill of Particulars ("BoP"). Dkt. 798 at 80. As Mr. Balwani explains in his motion to exclude evidence on the accuracy and reliability of tests run on unmodified commercial machines, such evidence related to non-Theranos technology would go beyond what the Indictment charged and is both irrelevant and prejudicial. Even if the government's argument extended only to non-BoP assays run on Theranos' proprietary technology, it would be unconvincing. The government's reasoning just confirms the prejudice that would result from admitting this evidence. The Indictment did not charge Mr. Balwani for deficient lab practices or violations of CLIA regulations. And the whole point of a BoP is to define the trial's scope. Going beyond that scope would invite the jury to convict for non-criminal regulatory violations. The government's argument that CMS "may have" found deficiencies for assays beyond those identified in the agency's report misses the mark. *See* Dkt. 1181 at 28–29. First, unless those alleged deficiencies relate to Theranos' proprietary fingerstick technology, they are irrelevant and prejudicial. Second, no factual or legal basis supports the government's request to essentially treat CMS's findings as symbolic—identifying specific deficiencies and concluding that those are a proxy for other unspecified problems whose existence the Court and the jury should apparently just presume. The government offers no authority for its speculative theory, and it would do nothing but confuse the jury about what Mr. Balwani is charged with.

Any emails or other documents that address both assays in the BoP and those that are not

can be redacted to mitigate their prejudicial effect.

The Loss of Theranos' LIS. The Court's earlier ruling on the LIS was unambiguous: (1) the government's claim that Theranos destroyed or failed to preserve the LIS is "not relevant under Rules 401 and 404(b)"; (2) the defense may argue that the missing LIS data is "critical to the Government's case" or that the government's anecdotal evidence is statistically insignificant without LIS; and (3) the Court deferred ruling on whether an argument at trial that "the LIS database is unavailable because of the Government's failure to obtain it" opens the door to the government presenting evidence of "Theranos' culpability in the destruction of the LIS." Dkt. 798 at 57–58.

Now, the government claims that even suggesting or arguing that the government has insufficient evidence to prove its case without LIS is the same as blaming the government for not preserving it. *See* Dkt. 1181 at 29. This is incorrect; pointing out that the government cannot meet its burden because it lacks crucial evidence is the essence of criminal defense, as the Court expressly recognized. Dkt. 798 at 57–58. Mr. Balwani acknowledged in his motion that if he puts on evidence at trial of the government's culpability for losing LIS, that may open the door to the government's introduction of evidence of fault. Dkt. 1156 at 12 n.6. Of course, the government would have to do so in good faith if those circumstances arise.[19]

[19] No matter how many times the government insinuates that there is "evidence linking [Mr. Balwani] himself to the relevant events," Dkt. 1181 at 29, the undisputed facts are that Mr. Balwani left Theranos more than two years before the government claims that Theranos destroyed the LIS, and that Mr. Balwani lacked any authority to direct or stop the disassembly of LIS. In any event, since the time it presented its story to the Court in Ms. Holmes' case, the factual foundation for the government's arguments on LIS has crumbled. Contrary to the government's past representations on which the Court relied, the government failed to preserve critical evidence despite ample opportunity to do so. *See* Dkt. 1156 at 15–16; Dkt. 1158; *see also supra* at 11–12 & n.9.

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Respectfully submitted,

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